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09/682,968	11/02/2001	Hans-Ulrich Demuth	20488-26DIV	3916
21710	7590	01/21/2004	EXAMINER	
BROWN, RUDNICK, BERLACK & ISRAELS, LLP. BOX IP, 18TH FLOOR ONE FINANCIAL CENTER BOSTON, MA 02111			MELLER, MICHAEL V	
			ART UNIT	PAPER NUMBER
			1654	

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 2

Application Number: 09/682,968
Filing Date: November 02, 2001
Appellant(s): DEMUTH ET AL.

John Serio
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/7/2003.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

The summary of invention contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is deficient because the appellant defines the invention as using effectors which raise the blood sugar level to treat hypoglycemia which is not true. As will be shown in the arguments to follow, only the inhibitors of DP (Dipeptidyl peptidase) IV maybe used to achieve the claimed invention. The effectors can either affect the activity of the DP IV enzymes negatively (inhibitor) or positively (activators) and since the invention is directed at reducing the activity of the DP IV enzymes then they must be negatively affecting the inhibitors (negative). Thus, the invention is limited to inhibition of the enzymatic activity and does not encompass any and all "effector".

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

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The rejection of claims 1-5 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

Darnell et al., Molecular Cell Biology, 1990, Scientific American Books, pg. 63.

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of administering to a mammal a therapeutically effective amount of an inhibitor of dipeptidyl peptidase (DPIV) and physiologically acceptable adjuvants and/or excipients for reducing in said mammal activity of endogenous DPIV, does not reasonably provide enablement for administering any and all effectors for reducing enzymatic activity of DPIV and DP IV-analogous

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enzymes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification is only enabled for a method of administering to a mammal a therapeutically effective amount of an inhibitor of dipeptidyl peptidase (IV) and physiologically acceptable adjuvants and/or excipients for reducing in said mammal activity of endogenous DPIV. The specification does **not** teach administering any and all effectors for reducing enzymatic activity of DPIV and DP IV-analogous enzymes as the claims recite.

The art of biotechnology is a highly unpredictable art and it would be an undue burden for one of ordinary skill in the art to test any and all effectors for reducing enzymatic activity of DPIV and DP IV-analogous enzymes. If it was so well known to one of ordinary skill in the art that any and all effectors for reducing enzymatic activity of DPIV and DP IV-analogous enzymes would work in the claimed method, then it would be clear from the prior art that such is the case. There is no prior art known to this examiner that establishes that one of ordinary skill in the art would have known at the time the invention was made that any and all effectors for reducing enzymatic activity of DPIV and DP IV-analogous enzymes would work in the claimed method otherwise it would have turned up in the prior art search and used against the instant claims.

Applicant has only shown in their examples the use of alanyl-pyrrolidid, isoleucyl-thiazolidide, the pseudosubstrates N-valyl-prolyl, O-benzoyl hydroxylamine, aminoacyl-thiazolidides, and isoleucyl-thiazolidide, see specification at pages 8-9. With only

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knowing these few inhibitors of DP IV, it is clear that such broad claims are not enabled by the instant specification when one of ordinary skill in the art is only given these limited amount of inhibitors. As is further evident also from claim 3, applicant intends to claim a very large and broad category of "effector for reducing enzymatic activity of DP IV" which there is simply not support in the specification for given the very limited disclosure. Enzyme are highly unpredictable and as such certain "effectors" may work while others may not, there is simply such a high unpredictability in the art, thus for one of ordinary skill in the art to know which of the effectors would work requires a great amount of undue experimentation.

Thus, the claims are unduly broad and do not find proper support from the instant specification. Thus, the rejection is properly made.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of the phrase, "an effector for reducing enzymatic activity of DPIV and DPIV analogous enzymes" in claim 1 is confusing. What does applicant mean by this ? It appears that the activity of DPIV is inhibited, thus such a term is more appropriate. Applicant needs to be more definite in what they mean. Also, it appears that "hypoglycemia" is misspelled.

Claims 1-5 are rejected under the judicially created doctrine of double patenting over claims 1-4 of U. S. Patent No. 6,319,893 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the claims in the parent patent (6,319,893) claim and inhibitor of the enzyme to be used in the claimed method. Applicant has claimed "an effector" or "a compound having a means for modulating enzymatic activity of DPIV and DPIV analogous enzymes" which is a broader interpretation of inhibiting as claimed in the parent application which is now patent no. 6, 319,893. Since "inhibiting" would read on these two terms the claims are rejected under this section.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

(11) Response to Argument

Appellant first argues that there is no evidence to support the 35 USC 112, first paragraph, enablement rejection. Appellant has provided the evidence themselves. The

reference by Darnell et al. in Molecular Cell Biology clearly defines that effectors have both positive (activators) and negative effects (inhibitors). It is clear from appellant's own reference that there is a clear scientific reasoning behind this rejection. Since the invention is reducing the activity of the DP IV enzyme, then it is clear that the enzyme is inhibited not activated because that would mean that the activity of the enzyme is also activated which it is not. The activity of the enzyme is decreased as is evidenced by the claims themselves.

Next, appellants argue that substrates and pseudosubstrates are also described as effectors in the specification and cannot be considered inhibitors thus they also further enable the term, "effectors of DP IV activity". This argument does not match the claim limitations. The claims recite "effector" for reducing enzymatic activity of DP IV.

Next appellant argues that the 35 USC 112, second paragraph rejection is inappropriate. They argue that the term, "effector" is definite and cite the Darnell et al. reference. The reason the claim is indefinite is because the term effector can mean both to positively (activate) and negatively (reduce) affect the activity of the DP IV enzymes. Since the claims clearly indicate that the invention reduces the activity of the DP IV enzymes then it does not make sense that the DP IV activity is effected it is inhibited only not activated.

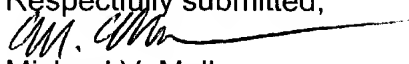
The double patenting rejection was not contested by appellants and will be maintained for the reasons of record.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

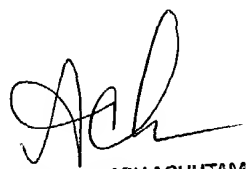

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January 13, 2004

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